UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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GARY ABELY, *Individually and on Behalf of All Others Similarly Situated*,

Plaintiff,

-against-

AETERNA ZENTARIS INC., JÜRGEN ENGEL, DENNIS TURPIN and PAUL BLAKE,

Defendants.

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12 Civ. 4711 (PKC)

MEMORANDUM AND ORDER

P. KEVIN CASTEL, District Judge:

Plaintiff Gary Abely brings this putative class action on behalf of investors who purchased shares and/or sold put contracts of defendant Aeterna Zentaris Inc. ("Aeterna") between June 1, 2009 and April 1, 2012 (the "Class Period"). According the plaintiff, Aeterna and the three individual defendants – Jürgen Engel, Dennis Turpin and Paul Blake – committed a fraud on the market by misrepresenting and omitting material information about the clinical trials of perifosine, a candidate drug for the treatment of advanced cancer. He asserts that defendants' alleged misrepresentations about perifosine's potential efficacy artificially inflated Aeterna share price, and that when the market learned that the drug was not, in fact, as effective as indicated, company share value plunged 76% from its Class Period high. Plaintiff brings securities fraud claims pursuant to sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "'34 Act"), 15 U.S.C. §§ 78j(b) and 78t, and Rule 10b-5, 17 C.F.R. § 240.10b-5.

The defendants move to dismiss, arguing that the Second Amended Securities Class Action Complaint (the "Complaint") fails to plead fraud with the particularity required of Rule 9(b), Fed. R. Civ. P., and the Private Securities Litigation Reform Act of 1995, 15 U.S.C. §

78u-4(b)(1) (the "PSLRA"). According to defendants, the Complaint fails to allege material misrepresentations and omissions, and does not adequately allege scienter or loss causation.

Separately, the plaintiff has moved to strike certain exhibits attached to the affidavit of Robert N. Kravitz. (Docket # 26.) He contends that the exhibits are not properly reviewed on a motion to dismiss and not subject to judicial notice under Rule 201, Fed. R. Evid.

For the reasons explained, the motion to dismiss is granted, and the motion to strike is denied.

BACKGROUND

For the purposes of defendants' motions, all non-conclusory factual allegations are accepted as true, see Ashcroft v. Iqbal, 556 U.S. 662 (2009), and all reasonable inferences are drawn in favor of the plaintiff as the non-movant. See In re Elevator Antitrust Litig., 502 F.3d 47, 50 (2d Cir. 2007).

I. The Phase 2 Clinical Trial.

Aeterna is headquartered in Quebec City, Canada, and focuses primarily on the development of drugs for oncology and endocrine therapy. (Compl't ¶ 11.) Its shares trade on NASDAQ. (Compl't ¶ 11.) Defendant Engel was Aeterna's president, chief executive officer and a director during the class period. (Compl't ¶ 12.) Defendant Turpin was the company's senior vice president and chief financial officer, and defendant Blake was the company's senior vice president and chief medical officer. (Compl't ¶¶ 13-14.)

In 2007, Aeterna began to focus on the development of a potential new cancer-treatment drug called perifosine. (Compl't ¶ 45.) Clinical trials of perifosine were previously undertaken in or around 1998 by a predecessor company of Aeterna, under the direction of

defendant Engel.[1] (Compl't ¶¶ 30-32.) Those earlier trials were limited, and showed mixed results. (Compl't ¶ 31.)

A regulation of the Food and Drug Administration ("FDA") provides for a three-phase clinical investigation of a proposed new drug. See 21 C.F.R. § 312.21. It states in part: "Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects." 21 C.F.R. § 312.21(b).

In 2007, Aeterna and its development partner, Keryx Biopharmaceuticals, Inc. ("Keryx"), took the first steps to initiate an exploratory, "Phase 2 placebo-controlled study of perifosine in combination with other single agent chemotherapies for metastic cancer patients." (Compl't ¶ 45.) Keryx and Aeterna entered into to a License and Cooperation Agreement for Perifosine (the "License Agreement"), pursuant to which Keryx "was responsible for conducting and testing perifosine in North America . . . ." (Compl't ¶ 32.) As discussed in greater detail, Keryx was responsible for key aspects of the clinical investigation, including the design and execution of the study and negotiation of necessary FDA approvals. Many of the alleged misstatements and omissions repeated conclusions that were first announced by Keryx. (Compl't ¶¶ 32, 60, 64, 84, 87, 107.) In exchange for its work on perifosine's development, Keryx would receive a license to sell perifosine in North America. (Compl't ¶ 32.) Perifosine's

[1] Perifosine was originally developed in the 1990s by Asta Medica GmbH, which later formed a spin-off company, Zentaris AG, that was acquired by Aeterna. (Compl't ¶¶ 25, 32.) Defendant Engel was affiliated with Asta Medica GmbH, and oversaw perifosine's initial development. (Compl't ¶ 32.)

development was overseen by a Coordination Committee that consisted of two representatives from Keryx and two from Aeterna. (Compl't ¶ 32.)

The Phase 2 trial was split into two distinct stages. (Compl't ¶ 47.) In the first stage, researchers treated terminally ill patients of at least seven types of cancer using either perifosine or placebo combined with one of eight other chemotherapy agents. (Compl't ¶ 45.) The study's primary objective was to determine progression at six months for patients who used perifosine in combination with a second chemotherapy agent, versus patients who were given non-perifosine placebo mixed with a chemotherapy agent. (Compl't ¶ 46.) The Phase 2 trial's initial protocol stated that if, at the completion of Stage 1, more than 30 percent of perifosine-treated patients were progression free, the study would be expanded to Stage 2. (Compl't ¶ 47.) That second stage was to be a hypothesis-confirming stage. (Compl't ¶ 47.)

Plaintiff maintains that the design of this first stage was inherently flawed. As described in the Complaint:

> The multiple arms of the study inherently increased the chances for a false positive conclusion, i.e., a spurious finding that perifosine provided a statistically significant benefit to colorectal cancer patients. . . . Aeterna never disclosed the number of different arms of this study, but given a minimum of seven types of cancer combined with eight different drugs which could be used for treatment of various types of cancer and the varying dosages, there were a minimum of ten arms and possibly dozens more.

(Compl't ¶ 45.) According to plaintiff, this first stage of the testing "was unexpectedly stopped early," and "amounted to little more than a data mining expedition to identify any arm of subgroup thereof that offered any glimpse of hope for treating some type of cancer." (Compl't ¶¶ 47-48.) Plaintiff asserts that Aeterna "cherry-picked 25 out of 381 patients" to support a hypothesis that perifosine had a clinical benefit. (Compl't ¶ 48.) In a press release dated June 1, 2009 – the first day of the class period – Aeterna announced that Keryx had presented positive

Phase 2 data to the American Society of Clinical Oncology, showing that perifosine combined with a chemotherapy agent called capecitabine had a statistically significant effect in slowing the progression of colon cancer. (Compl't ¶ 54.)

The second, hypothesis-confirming stage of the Phase 2 trial studied only patients with terminal, metastatic colorectal cancer, who were treated with perifosine in combination with capecitabine. (Compl't ¶ 49.) Although the trial's protocol called for 50 patients to be enrolled in this stage, Aeterna first enrolled only 25, and then later increased the number of enrollees to 38. (Compl't ¶ 49.) Plaintiff alleges numerous flaws in this second stage of the Phase 2 trial. (Compl't ¶ 49.) Defendants never disclosed whether, consistent with the study's original, stated objectives, 30% of enrollees were free of cancer progression at the six-month point. (Compl't ¶ 49.) According to plaintiff, contrary to standard procedures, the 25 unblinded patients from the first stage were included in stage two testing, thus introducing bias to the study and defeating the purpose of double-blind testing. (Compl't ¶ 49.) The Complaint asserts that defendants misrepresented to investors that the study continued to be double-blind, even though defendants knew the identities for 25 of the 38 stage-two patients. (Compl't ¶ 49.) According to plaintiff, the 25 unblinded patients showed statistically significant improvement in survival, while the 13 additional patients did not. (Compl't ¶ 49.) According to plaintiff, on May 9, 2011, when all data was unblinded, defendants then changed the trial's objectives "to fit the results," re-framing the primary objective as a study of the combination-treatment of capecitabine and perifosine without performing statistical adjustments to account for false positives. (Compl't ¶¶ 50-52.)

Plaintiff asserts that the defendants misstated and omitted material information concerning the Phase 2 trial. He asserts that a June 1, 2009 press release from Aeterna misleadingly attributed statistically significant results to the Phase 2 study and failed to account

for likely false positives. (Compl't ¶ 55.) Aeterna made numerous statements indicating that the Phase 2 findings were promising, including in SEC filings, press releases, investor presentations and investor conference calls from 2009 to 2012. (Compl't ¶¶ 57-61, 64-70, 74-81, 87-88, 90-95, 99-100, 107-10, 113-23, 129-30, 134-35.) For example, at a presentation at an investor conference in September 2011, defendant Blake stated that based on the Phase 2 study, the median survival rate for colorectal cancer patients treated with a combination of capecitabine and perifosine was 15 months, whereas the median survival rate for those treated with capecitabine and placebo was 6 months. (Compl't ¶ 129.) Blake described the results as "dramatic" and "unexpected," saying that they "gave rise to great enthusiasm in our company and in our partner company," as well as at the FDA. (Compl't ¶ 129.) According to plaintiff, defendants materially misstated the findings of the Phase 2 study and omitted material information that would have reflected negatively on the prospects of perifosine.

II. The Phase 3 X-PECT Clinical Trial.[2]

Plaintiff asserts that the defendants also are responsible for materially misrepresenting and omitting the duration of the Phase 3 trial of perifosine, thereby causing investors to infer positive interim results in the Phase 3 period. FDA regulation states: "Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects." 21 C.F.R. § 312.21(c).

[2] "X-PECT" is an abbreviation of "Xeloda® + Perifosine Evaluation in Colorectal cancer Treatment." (Compl't ¶ 71.) Xeloda is the brand name for capecitabine. (Compl't ¶ 78.)

On February 3, 2010, Keryx and the FDA agreed to a Special Protocol Assessment for a Phase 3 trial of perifosine. (Compl't ¶ 71.) On April 5, 2010, Aeterna announced that the FDA had given fast-track designation to the Phase 3 trial of perifosine. (Compl't ¶¶ 82-83.) A joint Aeterna-Keryx press release stated that FDA fast-track approval was intended to expedite development and agency review of drugs that had potential to address unmet medical needs for life-threatening conditions. (Compl't ¶ 82.) The press release described perifosine as a "novel, potentially first-in-class, oral anti-cancer agent" for the treatment of advanced colorectal cancer. (Compl't ¶ 82.)

Aeterna and Keryx began the Phase 3 trial on April 8, 2010. (Compl't ¶ 84.) During a conference call on May 13, 2010, defendant Engel stated that the Phase 3 trial involved approximately 430 patients at 40 different sites. (Compl't ¶ 90.) The number of patients ultimately expanded to 465. (Compl't ¶ 127.) Upon the 360th death among the study's patients, the data would be unblinded and analyzed. (Compl't ¶ 71.) Defendant Engel stated that Keryx was sponsoring and conducting the study, and expected that the trial would be complete in the second half of 2011. (Compl't ¶ 90.) Engel noted Keryx's expectation that the treatment would potentially be available to the public by mid-2012. (Compl't ¶ 90.) As the study progressed, Aeterna revised its prior estimate, and stated that the Phase 3 results would be available in the first quarter of 2012. (Compl't ¶ 129.)

According to the plaintiff, in repeated public statements about the estimated time required to complete the Phase 3 trial, the defendants knowingly or recklessly failed to explain that the trial could take more time to complete than its anticipated conclusion in the second half of 2011. (Compl't ¶¶ 91.) "As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable

to increased overall survival in those patients receiving perifosine." (See, e.g., Compl't ¶¶ 79, 83, 91, 93, 100, 103, 105.)

Plaintiff also asserts that defendants issued misleading statements about the prospects of success in the Phase 3 trial. In a March 28, 2012 investor conference call, Engel stated that he expected data from Phase 3 to be unblinded "during this month." (Compl't ¶ 139.) Blake stated: "I'm very confident we're going to get a good result in colorectal cancer. The Phase 2 data was strong." (Compl't ¶ 139.) Blake noted that "if the drug performs as we hope and expect from the protocol design, we should have a longer benefit on overall survival and I think we should have a very acceptable toxicity profile as well." (Compl't ¶ 139.) During this same call, Engel represented that he expected to release "top line results" within four to six weeks. (Compl't ¶ 139.) One analyst on the call pressed for more information concerning the timing of the 360th death and confirmation that it had not yet occurred. (Compl't ¶ 139.) Engel stated that "this will occur during the course of this month," and stated that following that event, researchers would ensure that anything "said about the results is absolutely correct, accurate and comprehensive and that will become available in the next four to six weeks." (Compl't ¶ 139.) When asked whether the "delay" in the trial completion had made Blake more optimistic about its success, Blake stated that he was "encouraged from the very beginning" of the study, noting the "pretty dramatic difference" between the placebo and perifosine treatments. (Compl't ¶ 139.)

III. The Announcement of the Phase 3 Trial Results.

On April 2, 2012, four days after indicating that the trial results were still four to six weeks away, Aeterna issued a press release stating in part that the Phase 3 trial "did not meet the primary endpoint of improving overall survival versus capecitabine + placebo." (Compl't ¶ 141.) Aeterna's stock price declined by $1.44 per share to $0.73, a drop of approximately 67%.

(Compl't ¶ 142.) Analysts noted that the results were announced several weeks earlier than expected. (Compl't ¶ 143.)

RULE 9(b), RULE 12(b)(6) AND THE PSLRA'S PLEADING THRESHOLD.

Pursuant to Rule 12(b)(6), Fed. R. Civ. P., "[t]o survive a motion to dismiss, a complaint must plead 'enough facts to state a claim to relief that is plausible on its face.'" ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co., 553 F.3d 187, 196 (2d Cir. 2009) (quoting Ruotolo v. City of New York, 514 F.3d 184, 188 (2d Cir. 2008)). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Iqbal, 556 U.S. at 678 (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

Along with the standards of Rule 12(b)(6), "[a]ny complaint alleging securities fraud must satisfy the heightened pleading requirements of the PSLRA and Fed. R. Civ. P. 9(b) by stating with particularity the circumstances constituting fraud." ECA, Local 134, 553 F.3d at 196 (citing Tellabs Inc. v. Makor Issues & Rights. Ltd., 551 U.S. 308 (2007)). Rule 9(b) requires a party to "state with particularity the circumstances constituting fraud or mistake." This pleading threshold gives a defendant notice of the plaintiff's claim, safeguards a defendant's reputation from "improvident" charges and protects against strike suits. See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007). "A securities fraud complaint based on misstatements must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." Id. at 99 (citing Novak v. Kasaks, 216 F.3d 300, 306 (2d Cir. 2000)). Allegations of fraud may be "too speculative even on a motion to dismiss," particularly

when premised on "'distorted inferences and speculations.'" Id. at 104 (quoting Segal v. Gordon, 467 F.2d 602, 606, 608 (2d Cir. 1972)).

"The PSLRA expanded on the Rule 9(b) standard, requiring that 'securities fraud complaints "specify" each misleading statement; that they set forth the facts "on which [a] belief" that a statement is misleading was "formed"; and that they state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" Anschutz Corp. v. Merrill Lynch & Co., 690 F.3d 98, 108 (2d Cir. 2012) (alteration in original) (quoting Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 345 (2005)). The PSLRA requires a complaint to "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). As the Second Circuit has repeatedly required, plaintiffs "must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so." Rombach v. Chang, 355 F.3d 164, 174 (2d Cir. 2004); accord Kleinman v. Elan Corp., plc, 706 F.3d 145, 152-53 (2d Cir. 2013); ATSI, 493 F.3d at 99 ("A securities fraud complaint based on misstatements must . . . explain why the statements were fraudulent. Allegations that are conclusory or unsupported by factual assertions are insufficient.") (citations omitted).

"Under section 10(b) and Rule 10b-5, 'an omission is actionable under the securities laws only when the [speaker] is subject to a duty to disclose the omitted facts.'" SEC v. DiBella, 587 F.3d 553, 563 (2d Cir. 2009). "For an undisclosed fact to be material, there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available."

Castellano v. Young & Rubicam, Inc., 257 F.3d 171, 180 (2d Cir. 2001) (quotation marks omitted). If a development renders a past statement misleading, the failure to disclose that development may be a material omission. In re Time Warner Inc. Sec. Litig., 9 F.3d 259, 267-68 (2d Cir.1993).

The PSLRA also "requires plaintiffs to state with particularity . . . the facts evidencing scienter, i.e., the defendant's intention 'to deceive, manipulate, or defraud.'" Tellabs, 551 U.S. at 313 (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 194 & n.12 (1976)). To qualify as "strong," the "inference of scienter must be more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Id. at 314.

DISCUSSION

I. The Complaint Fails to Allege Fraud with Particularity.

Defendants assert that the plaintiff has failed to allege material misstatements and omissions consistent with the requirements of Rule 9(b) and the PSLRA. Defendants argue that the Complaint has articulated a non-actionable critique of trial methodologies instead of identifying material misstatements or omissions about the trial.

The Second Circuit and other tribunals have concluded that the securities laws do not recognize a fraud claim premised on criticisms of a drug trial's methodology, so long as the methodology was not misleadingly described to investors. In Kleinman, the Second Circuit recently concluded that a plaintiff's criticisms of a clinical study's methodology cannot, in themselves, raise an actionable claim under the '34 Act. 706 F.3d at 153-55. Public statements about clinical studies need not incorporate all potentially relevant information or findings, or even adhere to the highest research standards, provided that its findings and methods are

described accurately. Id. The Ninth Circuit has similarly concluded that when a complaint "criticizes only the statistical methodology" in a study, it does "not adequately plead falsity with respect to statistics results." In re Rigel Pharmas., Inc. Sec. Litig., 697 F.3d 869, 879 (9th Cir. 2012). Defendants contend that, under this line of authority, the plaintiff's claims are non-actionable.

A. Plaintiff Does Not State a Claim that Defendants Falsely Described the Phase 2 Study as Double-Blind.

According to plaintiff, the defendants falsely characterized the Phase 2 trial as double-blind. (Compl't ¶¶ 69, 78, 92, 94, 107, 113, 134.) There is no dispute that during the first stage of the Phase 2 trial, 25 patients with colorectal cancer were administered perifosine-capecitabine in a double-blind study. (Compl't ¶¶ 47, 49.) According to the plaintiff, this arm of the study was unexpectedly halted early, with the patients unblinded and an unplanned interim analysis performed for safety and efficacy of the combination perifosine-capecitabine treatment. (Compl't ¶ 47.) Those 25 now-unblinded patients were then included in the second stage of the Phase 2 trial, along with an additional 13 patients. (Compl't ¶¶ 47, 49.)

Plaintiff's theory of fraud is that the trial's results were compromised because the 25 unblinded patients continued to participate in the Phase 2 trial, with defendants misrepresenting the study as "double blind." (Compl't ¶¶ 47, 49, 69, 78, 92, 94, 113, 134.) Plaintiff asserts that the continued participation of the unblinded patients undermined the study's integrity:

> The inclusion of the 25 unblinded enrollees in the confirmatory stage of the Phase 2 trial introduced the very bias that a true double blind study is designed to eliminate. Nevertheless, Defendants continued to represent to investors throughout the Class Period that the Phase II trial was a double blind study, even though they knew the results for 25 out of the 38 – ***or 66% of the enrollees*** – before Primary and Secondary Study Objectives for the confirmatory

> stage of the Phase II trial were established. Not surprisingly, the results from the 25 already unblinded patients showed a statistically significant benefit from the perifosine/capecitabine ("P-CAP") treatment, even when the results from the 13 additional enrollees showed no such benefit.

(Compl't ¶ 49; emphasis in original.)

As defendants note (Reply Mem. at 2), the Complaint does not define what constitutes a double-blind study or allege its relevance to evaluating a clinical trial's results. The Court takes judicial notice that, commonly, in a double-blind study, patients and investigators alike are not told which patients receive placebo and which receive the trial drug, in an attempt to avoid biases that might arise from differential care or treatment. See Guidance for Industry: E 10 Choice of Control Group and Related Issues in Clinical Trials (May 2001).[3] As noted by the defendants, the Complaint alleges that following the first stage of the Phase 2 study, the sponsors unblinded and analyzed the results to determine whether the perifosine-capecitabine treatment was effective in any of the research arms, and then expanded the study to include 13 additional colorectal patients to determine whether they, too, benefited from perifosine-capecitabine treatment.

The Second Circuit has emphasized that in scrutinizing a section 10(b) claim, a court does not judge the methodology of a drug trial, but whether a defendant's statements about that study were false and misleading. Kleinman, 706 F.3d at 154-55. In Kleinman, defendants' post-hoc analysis that "deviated from the established protocol" did not support a fraud claim when defendants' press release truthfully disclosed that a study's only positive results came from

[3] As described in the Guidance to Industry, § I(B)(2): "Clinical trials are often double-blind (or double-masked), meaning that both subjects and investigators, as well as sponsor or investigator staff involved in the treatment or clinical evaluation of subjects, are unaware of each subject's assigned treatment. Blinding is intended to minimize the potential biases resulting from differences in management, treatment, or assessment of patients, or interpretation of results that could arise as a result of subject or investigator knowledge of the assigned treatment." See http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm125912.pdf (emphasis in original).

a post-hoc analysis. Id.; accord In re Rigel, 697 F.3d at 877 (plaintiff did not allege fraudulent misstatements "based on [a] contention that Defendants should have used a particular statistical methodology, which [is] described in the complaint."). In re Adolor Corporation Securities Litigation, 616 F. Supp. 2d 551, 566-67 (E.D. Pa. 2009), concluded that the plaintiffs failed to allege material misstatements when defendants described a clinical study as double-blinded. Plaintiffs failed to allege that the study's design was contrary to the FDA's guidance on the conduct of a double-blind study, and failed to provide an industry or regulatory definition of what constitutes a double-blind study. Id. at 567. "Without allegations that Defendants' use of the term directly contradicted either the FDA's definition or common industry usage, Defendants' statements regarding the double-blinded nature of the . . . trials could not have been false or misleading when made." Id.

Plaintiff's allegations as to the study's use of the phrase "double blind" suffers from the same infirmity. The Complaint fails to allege a generally accepted standard for conducting a double-blind study. While the Court takes judicial notice of the FDA's guidance as to double-blind studies, the Complaint does not allege with particularity how the defendants' approach – i.e., the segmented, multi-stage use of a double-blind population in the Phase 2 study – materially contravenes that guidance. At most, as in Kleinman, the Complaint asserts that the defendants did not conduct the Phase 2 study pursuant to plaintiff's preferred methodology, but does not allege with particularity how the defendants' description of the study as "double blind" was a material misstatement.

Moreover, the Complaint's own description of the study's protocol acknowledges that the Phase 2 study was to be expanded in its second stage if the first stage showed patient improvement: "According to the protocol, if after the completion of Stage 1, more than 30% of

perifosine patients were progression-free, the study would be expanded into Stage 2, the hypothesis confirming stage of the study." (Compl't ¶ 47.) This allegation tracks the published text of the protocol: "If there is any evidence of improved time to progression in any tumor type with any of the drugs to be evaluated, the initial study or component(s) of the study will be expanded to increase the certainty that this is an effect of perifosine." (Kravitz Aff't Ex. L at 1.)[4] Plaintiff does not allege that the 25 initial patients were not, in fact, treated on a double-blind basis prior to the analysis of the first stage's results, or that the additional 13 patients added in the second stage were not then treated on a double-blind basis. The study was expanded, as indicated in the publicly available protocol. The Complaint also does not articulate how the study would have proceeded to the second, hypothesis-confirming stage without the unblinding and analysis of the initial, double-blind study of the 25 patients.

The Complaint fails to allege with particularity that the defendants made a material misstatement by characterizing the Phase 2 study as double-blind.

B. Plaintiff Does Not Adequately Allege that Defendants Misrepresented or Omitted Material Information About the Design of the Phase 2 Study.

Plaintiff also contends that the defendants misrepresented or omitted material information about the design and findings of the Phase 2 study. According to plaintiff, the study was organized in a way that heightened the likelihood of yielding a false positive, and permitted defendants to manipulate the data toward a seemingly successful outcome. Plaintiff asserts that the study's design included numerous flaws that misled shareholders into overestimating the likely efficacy of the perifosine-capecitabine combination treatment.

[4] As will be discussed later when reviewing plaintiff's motion to strike, the published protocols of the perifosine study are properly considered on a motion to dismiss, because they are both integral to the Complaint's allegation and properly subject to judicial notice under Rule 201(b), Fed. R. Civ. P.

For the reasons explained, plaintiff's allegations amount to a non-actionable critique of defendants' study design.

1. Plaintiff's Allegations Concerning the Multiple Arms of the Phase 2 Study Do Not Allege Securities Fraud.

In the first stage of the Phase 2 study, at least seven categories of cancer patients received perifosine in combination with one of eight chemotherapy regimens. (Compl't ¶ 45.) Plaintiff asserts that there were at least 10 research arms of perifosine combination treatments, and potentially dozens more, but that defendants failed to disclose the results of any research arm other than perifosine-capecitabine treatment for colorectal cancer. (Compl't ¶¶ 45, 47.) Plaintiff asserts that the use of multiple research arms gave defendants several opportunities to identify a statistically significant benefit, and heightened the likelihood of finding a false positive. (Compl't ¶¶ 45, 48-49.)

As noted, Kleinman concluded that disagreements over a study's methodology do not, standing alone, raise an inference of securities fraud. 706 F.3d at 153-55. The plaintiff in Kleinman brought '34 Act claims alleging that defendants materially misstated and omitted information about the results of a Phase 2 study for a drug to treat Alzheimer's Disease. Id. at 147-51. The Second Circuit concluded that plaintiff failed to allege material misstatements and omissions, and instead set forth a non-actionable critique of defendants' overall study design. For instance, defendants did not disclose that one control group showed a larger-than-expected cognitive deterioration, which, as a consequence, allegedly exaggerated the drug's efficacy in the published results. Id. at 154. Kleinman concluded that defendants had no obligation to disclose the results of that particular control group, noting that "[d]efendants are not required to adopt [plaintiff's] view" as to whether the results were aberrational. Id. The plaintiff also alleged that defendants should have disclosed that a post-hoc analysis performed on the study was

curvilinear; Kleinman concluded that it was sufficient for defendants to disclose that the study included post-hoc analysis, and that the securities laws did not require them to specify a particular category of that analysis. Id. at 154-55. Plaintiff also failed to allege that a press release contained actionable omissions concerning the drug's lack of short-term efficacy and its failure to enumerate particular side effects, when defendants made no representation that the drug was effective in the short term and reported "serious adverse events" for those treated with the drug as compared to those given placebo. Id. at 155.

In addition, the Ninth Circuit has observed that "the securities laws do not require that companies report information only from optimal studies, even assuming that scientists could agree on what is optimal . . . ." In re Rigel, 697 F.3d at 879. Moreover, "companies reporting information from imperfect studies are not required to disclose alternative methods for interpreting the data." Id. In re Rigel also indicated in dictum that if a defendant inaccurately reports its own statistical analysis, or alters a study's methods after reviewing raw data, such conduct may be actionable under the '34 Act. Id. at 877.

In this case, plaintiff's critiques all go toward the design of the study and not to the existence of actionable misrepresentations or omissions. (Compl't ¶¶ 45, 47-49.) The published protocol of the Phase 2 study expressly specified the categories of cancer that would be studied and the seven chemotherapy drugs that would be studied in combination with perifosine. (Kravitz Dec. Ex. L.) Specifically, it disclosed that the study would examine patients with breast, non-small cell lung, colorectal, prostate, ovarian and head and neck cancers. (Kravitz Dec. Ex. L at 2.) Plaintiff does not allege that the existence of these multiple research arms was undisclosed or misleadingly described. Thus, his allegations that the Phase 2 trial included too many research arms and invited false positives merely amount to a competing view

of how the trial should have been designed, not an allegation of material misstatement or omission. They do not raise an actionable claim of securities fraud. See Kleinman, 706 F.3d at 154-55; In re Rigel, 697 F.3d at 879.

2. Plaintiff Does Not Allege Actionable Omissions Concerning Certain Discrete Findings in the Phase 2 Trial.

Plaintiff alleges that defendants failed to disclose whether 90% of the trial participants reached the primary study objective, and, in particular, did not publish the results for breast cancer patients treated with perifosine-capecitabine. (Compl't ¶¶ 45, 49.) According to plaintiff, discouraging results of the same combination of treatment for a different category of tumor should have raised a red flag about the effectiveness of perifosine-capecitabine. (Compl't ¶ 45.) Next, plaintiff alleges that defendants cherry picked their analysis of Phase 2 results by concentrating on the 25 patients with colorectal cancer who received perifosine-capecitabine treatment, representing just 6.6% of enrollees in the first part of the Phase 2 trial. (Compl't ¶¶ 48-49, 52.) Plaintiff also asserts that defendants misrepresented the results of the study by describing a "statistically significant improvement" in survival, even though the 13 additional colorectal patients that were added for the second portion of the Phase 2 trial showed no sign of improvement. (Compl't ¶ 49.)

Absent a regulatory obligation, an omission is actionable "only" when additional disclosure is "necessary 'to make statements made, in light of the circumstances under which they were made, not misleading.'" Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1321 (2011) (ellipsis in original) (quoting Rule 10b-5). "Even with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under [section 10(b) and Rule 10b-5] by controlling what they say to the market." Id. at 1322. The Phase 2 trial's findings as to breast cancer patients, and as to the overall patient population,

may have been of interest to shareholders, or provided context to evaluate the findings on colorectal cancer, but relevance alone does not trigger the duty to disclose. In addition, defendants' focus on the colorectal cancer patients arose from the fact that those patients showed promising results during the Phase 2 trial, which was itself designed to test whether a perifosine combination treatment could be efficacious. Plaintiff does not plausibly allege how the securities laws obligated defendants to make additional disclosures about other patient populations.

Moreover, plaintiff's contention that disclosure was required for patients with other forms of cancer is analogous to the Kleinman plaintiff's assertion that defendants should have disclosed the allegedly dramatic deterioration in a particular control group in order to provide context for the seemingly promising conclusions. 706 F.3d at 154. Defendants are not obligated to adopt plaintiff's views as to which segments of a trial's population are most relevant, and plaintiff has not directed the Court to any material statements about the study as it related to patients with breast cancer, or patient in any other arm of the study, that were misleading and in need of correction. Again, that such information might have provided useful context for investors does not rise to the level of an actionable omission. See generally Matrixx, 131 S. Ct. at 1321-22.

For the same reason, plaintiff fails to state a claim that the defendants misrepresented the results of the Phase 2 trial by not disclosing that the 13 additional colorectal patients added to the second stage of the Phase 2 trial failed show improvement when treated with perifosine-capecitabine. Defendants did not represent that those 13 patients, in isolation, reflected a statistically significant benefit, and plaintiff does not allege that a pool of 13 patients is large enough to accurately discern whether a test's results have statistical significance. Again, plaintiff does not dispute that, under the defendants' methodology, the Phase 2 results found

statistically significant improvement to patients given perifosine-capecitabine: he asserts instead that the underlying study design was itself flawed. The protocol stated that "[i]f there is any evidence of improved time to progression in any tumor type with any of the drugs to be evaluated, the initial study or component(s) of the study will be expanded to increase the certainty that this is an effect of perifosine." (Kravitz Dec. Ex. L. at 1.) The Complaint does not allege with particularity why further disclosure about the 13 additional patients was required to correct a past misstatement, Matrixx, 131 S. Ct. at 1321-22, or why the '34 Act required defendants to incorporate plaintiff's preferred mode of analysis for the study, Kleinman, 706 F.3d at 154. See also In re Rigel, 697 F.3d 879 ("Because Plaintiff does not allege that Defendants misrepresented their own statistical methodology, analysis, and conclusions, but instead criticizes only the statistical methodology employed by Defendants, Plaintiff did not adequately plead falsity with respect to statistic results.").

Plaintiff states that the Phase 2 trial warranted further research into perifosine-capecitabine treatment, and that his claims are directed only to the alleged misimpression that perifosine was likely to be effective. In his opposition memo, plaintiff states that he "does not contend that any of these steps were improper for an exploratory Phase 2 trial, nor that the results were insufficient to warrant a Phase 3 trial," and argues instead that once defendants announced the trial's preliminary findings, they had a duty to "either make some form of multiplicity adjustments to those results or to disclose the information required for investors to make such adjustments so they could properly evaluate the risk that perifosine would fail in Phase 3 testing." (Opp. Mem. at 8.) But In re Rigel rejects this proposition, and states: "Section 10(b) and Rule 10b-5 do not categorically prohibit statements that are incomplete or that report

cumulative figures instead of detailed breakdowns of the underlying data or subcategories of data." 697 F.3d at 879 n.7.

Plaintiff separately contends that, after the conclusion of the Phase 2 trial, defendants analyzed "a miniscule subset" of colorectal perifosine-capecitabine patients, and misleadingly described that analysis as finding "a highly statistically significant benefit" from administering perifosine-capecitabine, more than doubling patients' survival time. (Opp. Mem. at 19-20; Compl't ¶¶ 69, 76, 78, 113, 134.) Plaintiff alleges that the following statement misleadingly described the additional analysis:

> Results showed improvement in both time to progression and overall survival in the perifosine capecitabine arm versus placebo capecitabine. Of notable interest and for the first time presented were data showing a highly statistically significant benefit in median overall survival, 15.3 months versus 6.8 months, and time to progression, 18 weeks to 10 weeks for the subset of patients who were refractory to a 5-FU chemotherapy-based treatment regimen.[5]

(Compl't ¶ 76; see also Compl't ¶ 69, 78, 113, 134.)

While plaintiff characterizes this analysis as directed to a "miniscule subset" of patients, the number of patients was disclosed in the press release announcing the study's results, and consisted of 14 patients who received perifosine-capecitabine and 11 who received capecitabine with placebo. (see, e.g., Compl't ¶¶ 69, 78.) Whether characterized as a "miniscule subset," or something else, the number of patients analyzed in this subset was disclosed. Plaintiff's contention that the analysis of this subgroup was misrepresented as showing a "highly statistically significant" survival benefit, and that the securities laws required additional statistical analysis to exclude false positives, does not allege fraud with particularity. For instance, In re Rigel rejected plaintiff's claim that defendants should have revised their statistical

[5] As described in Aeterna filings, capecitabine is "a 5-FU pro-drug," with 5-FU being "a core component" to colorectal chemotherapy regimens FOLFIRI and FOLFOX. (Compl't ¶¶ 69, 134.)

analysis by "calculating separate p-values for the United States and Mexico and combining those results using 'Fisher's method,' and using 'Tukey's Studentized Range test.'" 697 F.3d at 877. "[M]erely alleging that defendants should have used different statistical methodology in their drug trials is not sufficient to allege falsity." Id. at 878; see also In re MELA Sciences, Inc. Sec. Litig., 2012 WL 4466604, at *13 (S.D.N.Y. Sept. 19, 2012) (allegation of "unsound statistical analysis" in a clinical study does not support a securities fraud claim, and "are essentially no different than opinions."); In re Sanofi-Aventis Sec. Litig., 774 F. Supp. 2d 549, 567 (S.D.N.Y. 2011) ("Plaintiffs cannot premise a fraud claim upon a mere disagreement with how sanofi chose to interpret the results.").

Lastly, plaintiff contends that defendants' arguments amount to a truth-on-the-market defense, and that the issues raised in the Complaint are not susceptible to the fact-intensive, truth-on-the-market inquiry at the motion to dismiss stage. See generally Ganino v. Citizen Util. Co., 228 F.3d 154, 167-68 (2d Cir. 2000); In re Bank of Am. Corp. Sec., Deriv. & ERISA Litig., 757 F. Supp. 2d 260, 300-02 (S.D.N.Y. 2010). This argument misconstrues the defendants' motion, which does not assert a truth-on-the-market defense. Defendants do not contend that, for example, the market was aware of the Phase 2 results as to breast cancer patients (Opp. Mem. at 22), but rather, that they were under no obligation to release that data.

The Complaint fails to allege that the defendants omitted material information concerning the Phase 2 trial.

C. Plaintiff Does Not Allege with Particularity that Defendants Fraudulently Manipulated Testing Procedures.

Plaintiff also asserts that the defendants manipulated the Phase 2 trial in order to "rig" promising-sounding results that would help Aeterna remain solvent. (See Opp. Mem. at 23-26.) This contention incorporates the alleged misstatements and omissions previously

discussed. Construing the Complaint in the light most favorable to the plaintiff, he appears to contend that, cumulatively, these flaws in the study reflect an overall scheme to guide its results, and that the scheme was facilitated by Aeterna's representatives on the trial's Coordination Committee.

Plaintiff identifies the six components of the manipulation: 1.) the undisclosed number of treatment arms (Compl't ¶¶ 49, 52); 2.) the premature termination of the first stage of the study, followed by analysis of a small portion of the study population (Compl't ¶¶ 47, 52); 3.) the continued study of the 25 colorectal cancer patients in the hypothesis-confirming portion of the Phase 2 trial (Compl't ¶¶ 49, 52); 4.) the failure to perform statistical adjustments for the colorectal cancer research arm, or to disclose data about the other research arms (Compl't ¶¶ 47, 52); and 5.) changes made to the primary study objective and secondary study objective following the unblinding of Phase 2 data. (Compl't ¶¶ 50, 52.)

For the reasons previously explained, these allegations fail to allege with particularity that these alleged manipulations, individually, constitute actionable misstatements or omissions. Plaintiff's apparent theory that they collectively reflect a scheme to manipulate the test suffers from the same underlying infirmity as the other alleged flaws in the trial: it is not directed toward misrepresentations or omissions about the conduct of the trial, but to its methodology.

Plaintiff notes in particular the shifting objectives of the Phase 2 trial. Initially, the study's primary objective was to identify whether 30% of patients were progression-free after six months. (Compl't ¶ 50.) The primary objective was then changed "[t]o determine the time to tumor progression when receiving single agent chemotherapy (capecitabine) in combination with perifosine in comparison to patients receiving single agent chemotherapy (capecitabine) alone

(i.e., with placebo)." (Compl't ¶ 50.) The trial also added another secondary objective: "Overall survival will be evaluated." (Compl't ¶ 50.) Plaintiff alleges that defendants changed the primary and secondary study objectives to fit the known results, in violation of typical protocols for a clinical trial. (Compl't ¶ 52.)

The original protocol, however, allowed for the possibility that the Phase 2 trial or its components would be altered, depending on its interim findings. (Kravitz Dec. Ex. L.) The trial's protocol, as published on November 13, 2006, stated that "[t]he primary goal of this trial is to obtain a preliminary and objective assessment of the effects of perifosine on time to progression." (Id. at 1.) "If there is any evidence of improved time to progression in any tumor type with any of the drugs to be evaluated, the initial study or component(s) of the study will be expanded to increase the certainty that this is an effect of perifosine." (Id. at 1; emphasis added.) The FDA contemplated such changes to a study's protocol when it proposed its three-phase study rule.[6] Here, the original protocol was updated twelve times. See History of NCT00398879, available at http://clinicaltrials.gov/archive/NCT00398879. Plaintiff does not allege that these changes to the protocol – versions of which are publicly available on a website maintained by the National Institutes of Health – were undisclosed. Federal law requires the publication and filing of this information.[7] On September 22, 2009, the protocol was revised to

[6] "A protocol for a Phase 2 or 3 investigation should be designed in such a way that, if the sponsor anticipates that some deviation from the study design may become necessary as the investigation progresses, alternatives or contingencies to provide for such deviation are built into the protocols at the outset." Phases of an Investigation, 52 Fed. Reg. 8798-01, 8834 (Mar. 19, 1987).

[7] As described at http://clinicaltrials.gov/ct2/about-site/background:

> ClinicalTrials.gov was created as a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA required the U.S. Department of Health and Human Services, through NIH, to establish a registry of clinical trials information for both federally and privately funded trials conducted under investigational new drug applications (IND) to test the effectiveness of experimental drugs for serious or life-threatening diseases or conditions. NIH and the Food and Drug Administration (FDA) worked together to develop the site, which was made available to the public in February 2000.

state that the trial was closed to new enrollees except as to patients with metastatic colon cancer, who would be randomized to be treated with capecitabine plus perifosine, or, alternatively, capecitabine plus placebo. Id. On May 9, 2011, the protocol was updated to state that the primary study objective was no longer to determine the proportion of progression-free patients at six months, but to determine the time to tumor progression for colorectal patients receiving the perifosine-capecitabine combination. Id. As plaintiff notes, the protocol added a secondary goal of evaluating overall survival. Id.

Assuming arguendo that the changes made to the study's primary and secondary objectives are contrary to the standards normally expected in a clinical trial, it is nevertheless the case that these revisions were disclosed to the public. Plaintiff does not allege that the objectives were concealed or inaccurately described. Moreover, the trial's organizers stated from the outset that the study would be expanded in the event that any evidence showed that perifosine was effective in treating the time of progression for a given type of tumor. (Kravitz Dec. Ex. L.) The protocol was thereafter updated to reflect that it was investigating effectiveness of treatment for colorectal cancer, and that the primary endpoint was to investigate tumor progression for patients receiving the perifosine-capecitabine combination. Plaintiff does not allege that these changes to the Phase 2 trial were concealed from the investing public, but that they reflect a scheme to manipulate the trial toward a seemingly favorable outcome. Similarly, plaintiff does not allege

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The ClinicalTrials.gov registration requirements were expanded after Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 801 of FDAAA (FDAAA 801) requires more types of trials to be registered and additional trial registration information to be submitted. The law also requires the submission of results for certain trials. This led to the development of the ClinicalTrials.gov results database, which contains information on study participants and a summary of study outcomes, including adverse events. The results database was made available to the public in September 2008. FDAAA 801 also established penalties for failing to register or submit the results of trials.

that the defendants misstated these changes to the protocol – only that they should not have been made.

Plaintiff relies heavily on United States v. Harkonen, 2010 WL 2985257 (N.D. Cal. July 27, 2010), in which the district court upheld a jury's guilty verdict of criminal wire fraud against a company executive who was found to have manipulated Phase 3 study data to reflect a more favorable outcome. But the evidence in Harkonen showed a corporate officer's intentional, post-hoc manipulation of Phase 3 data, following preliminary analysis that a proposed new lung-disease drug did not produce statistically significant improvement under any of the study's original objectives. Id. at *7-8. The defendant never disclosed that the trial failed to reach its primary endpoint or all 10 of its secondary endpoints, and issued a misleading press release that described the results of the Phase 3 study as a success. Id. at *7-10. At the defendant's direction, the company undertook post-hoc analysis of the raw data and issued a press release that portrayed the clinical trial as demonstrating a statistically significant "survival benefit" that reduced mortality in a patient subgroup by 70%. Id. at *8-9. The district court concluded that there was sufficient evidence to support the jury's conclusion that the press release was objectively untrue. Id. at *9-11. It also upheld the jury's conclusion that the defendant knew that the press release's content was false, and that the defendant acted with fraudulent intent. Id. at *12-14.

In this case, by contrast, the alteration of the primary endpoint was made publicly and contemporaneously, as was the addition of a third secondary endpoint. (Compl't ¶ 50.) Harkonen also reviewed testimony that most typically, subgroup analysis within the patient population is used in a study's hypothesis-generating stage, as opposed to the defendant's analysis that was undertaken once all Phase 3 evidence was gathered. 2010 WL 2985257, at *7.

Here, however, the subgroup analysis of colorectal cancer patients and the change in the study's primary endpoint occurred during the first of two stages in the Phase 2 trial. (Compl't ¶¶ 50, 52.) The study therefore shifted its resources toward confirming a preliminary hypothesis of perifosine-capecitabine efficacy in treating terminally ill colorectal cancer patients. Thus, the open and public amendments of the trial's primary endpoint, which occurred prior to the hypothesis-confirming stage, were substantially different from the conduct in Harkonen, when, at the study's conclusion, the defendant orchestrated and publicly presented an analysis that was never part of the underlying trial.

Again, plaintiff alleges that, at most, the defendants did not engage in best practices in the design and conduct of the Phase 2 study, but such allegations are insufficient to allege material misstatements or omissions.

D. Plaintiff Does Not Allege that Defendants Misrepresented the Timing of the Phase 3 Trial Results.

On May 18, 2011, when discussing the design of the Phase 3 trial during an analyst conference call, defendants indicated that they expected results to be released in the fourth quarter of 2011. (Compl't ¶ 118.) The Phase 3 trial was scheduled to conclude upon the death of its 360th patient. (See, e.g., Compl't ¶¶ 71, 92.) In the May 18 call, an analyst asked defendant Blake whether the trial's results would be announced later than 2011 if the patient survival exceeded expectations. (Compl't ¶ 118.) Defendant Blake stated that this was "a very interesting and tough question" and that "I don't want to be unduly or over optimistic. I think we've been appropriately cautious in the design of the study." (Compl't ¶ 118.) Blake stated that "we are very pleased with the Phase II data we saw, and we're very pleased with the Phase III progress we're seeing now." (Compl't ¶ 118.)

On March 28, 2012, Engel and Blake told analysts that the 360th patient death – the planned conclusion of the study – had not yet occurred, and that following that event, an additional four to six weeks would be needed to clean the data before releasing the results. (Compl't ¶ 139.) However, four days later, on April 4, 2012, Aeterna announced that the Phase 3 trial "did not meet the primary endpoint in improving overall survival" for patients receiving perifosine and capecitabine, versus patients who received capecitabine and placebo. (Compl't ¶ 141.)

According to plaintiff, the defendants delayed release of the Phase 3 results in an attempt to mislead the market into concluding that the trial was exceeding expectations as to the survival rate of patients receiving perifosine-capecitabine. At the same time, Aeterna was preparing for a March 15, 2012 secondary offering of common stock, which plaintiff contends, motivated defendants to delay announcing the trial's results and to maintain Aeterna's allegedly inflated share value. (Compl't ¶¶ 106, 133, 136.)

The Complaint alleges that defendants knew or recklessly disregarded the fact that the Phase 3 trial "would (or could) be completed later than the second half of 2011 even if perifosine was ineffective," and that by failing to expressly disclose this fact, "investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine." (Compl't ¶¶ 72, 83, 85, 91(d), 93(e), 100(d).) Plaintiff's theory appears to be that because the defendants did not expressly disclaim a potential inference that could be drawn from the timing of the study's results, they committed an actionable, material omission.

But the Complaint also quotes statements from defendants in which they refrained from suggesting that a delay in results should be interpreted as a sign of the trial's success. As

noted, in May 2011, when directly questioned about whether a successful study would delay results past 2011, Blake described the question as "tough" and "interesting," and stated, "I don't want to be unduly or over optimistic." (Compl't ¶ 118.) In the March 28, 2012 conference call, an analyst asked Blake whether the delay in the death of the 360th patient had made him optimistic about the study's outcome. (Compl't ¶ 139.) Blake stated that he had "been encouraged from the very beginning," but added, "I have no idea what the data show." (Compl't ¶ 139.) He stated that the acceptance of the study design by regulators and investigators "points to my quiet confidence but obviously no one can be certain of the data until we see what the data tell us." (Compl't ¶ 139.)

Plaintiff has not alleged an actionable omission based on defendants' failure to expressly foreclose a potential investor inference. A reasonable investor might, in fact, have inferred that the delay of the study's conclusion from the fourth quarter of 2011 to March 2012 augured well for the trial's results. As defendants noted, a reasonable investor also might have inferred that the delay was caused by low mortality in patients treated with placebo or the need for researchers to analyze and scrutinize the raw data. Plaintiff does not allege that defendants invited any particular conclusions that should be drawn from the timing of the results' release. He therefore fails to allege that disclosure was required to render a past statement not misleading, In re Time Warner, 9 F.3d at 267-68.

II. The Complaint Fails to Raise a Strong Inference of Scienter.

In addition to the Complaint's failure to allege misleading statements or omissions with the particularity required of Rule 9(b) and the PSLRA, it also is dismissed for its failure to allege facts giving rise to a strong inference of scienter.

The PSLRA requires a plaintiff to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C.A. § 78u-4(b)(2)(A). "This standard requires courts to take into account 'plausible opposing inferences.'" Matrixx, 131 S. Ct. at 1324 (citing Tellabs, 551 U.S. at 323). A plaintiff successfully alleges scienter "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324. In reviewing scienter allegations, the court should consider "all the allegations holistically." Id. at 326.

Two states of mind may constitute scienter. One reflects a defendant's motive and opportunity to commit fraud, as manifested in conduct that benefits the defendants "in some concrete and personal way." ECA, Local 134, 553 F.3d at 198. "Motives that are common to most corporate officers, such as the desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation, do not constitute 'motive' for purposes of this inquiry." Id. Motive is most frequently established by evidence that insiders made a misrepresentation to sell their own shares at a profit. Id.

Alternatively, a plaintiff may plead scienter through "strong circumstantial evidence" of recklessness. ATSI, 493 F.3d at 99. The Second Circuit has stated that "securities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements. Under such circumstances, defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation." Novak, 216 F.3d at 308. This recklessness is "an extreme departure from the standards of ordinary care . . . ." Id. "At least four circumstances may give rise to a strong inference of the requisite

scienter: where the complaint sufficiently alleges that the defendants (1) 'benefitted in a concrete and personal way from the purported fraud'; (2) 'engaged in deliberately illegal behavior'; (3) 'knew facts or had access to information suggesting that their public statements were not accurate'; or (4) 'failed to check information they had a duty to monitor.'" ECA, Local 134, 553 F.3d at 199 (quoting Novak, 216 F.3d at 311). "'[T]he strength of the circumstantial allegations must be correspondingly greater' if there is no motive." Id. (quoting Kalnit v. Eichler, 264 F.3d 131, 142 (2d Cir. 2001)).

Plaintiff asserts that, under either the motive-and-opportunity framework or a recklessness analysis, the Complaint raises a strong inference of scienter. (Opp. Mem. at 28-33.) He alleges that the defendants had the access and expertise required to manipulate the study data. Perifosine was developed pursuant to the License Agreement between Keryx and Aeterna. (Compl't ¶¶ 32, 144.) Under the License Agreement, both companies appointed two "professionally and technically qualified" members of a Coordination Committee that was responsible for studies of perifosine. (Compl't ¶¶ 144.) The committee's responsibilities included the "development and validation of analytical methodology necessary to process validation and product release testing." (Compl't ¶ 144.) Its actions, including any amendments to the development plan, required unanimous consent from all members. (Compl't ¶ 144.) The License Agreement called for a free flow of data between Keryx and Aeterna. (Compl't ¶ 148.)

Plaintiff alleges that through Aeterna's representatives on the Coordination Committee, the defendants had access to all relevant information about perifosine's development. (Compl't ¶¶ 32, 144.) Plaintiff asserts that defendants Engel and Blake were highly knowledgeable about drug development, testing and analysis, held advance scientific degrees, and participated in numerous new drug studies. (Compl't ¶¶ 145-47.) The Complaint

asserts that based upon their background and knowledge, Engel and Blake "were professionally and technically qualified to serve on the Coordination Committee." (Compl't ¶ 148.)

He also alleges that during the class period, defendants represented that there was cooperation and a free flow of data between Keryx and the defendants, and that defendants intended to use the results of the trial to secure regulatory approval to market perifosine in Europe. (Compl't ¶ 148.) According to plaintiff, despite their knowledge of drug development, testing and statistical analysis, and the flow of data between Aeterna and Keryx, the defendants nevertheless misrepresented the statistical significance of Phase 2 results, permitted the trial to proceed to Phase 3 and did not disclose material information concerning the results of the Phase 2 study. (Compl't ¶ 149.)

Plaintiff alleges that defendants were motivated to artificially inflate Aeterna share price due to both the company's financial struggles and its ongoing share offerings. (Compl't ¶¶ 150-51.) According to the Complaint, in mid-2009, Aeterna had "a burn rate of over $50 million per year." (Compl't ¶ 150.) One of its two primary drug candidates had failed in Phase 3 testing, and company share value "was languishing to the point [that it] was facing de-listing of its stock by NASDAQ GM." (Compl't ¶ 150.) By the end of 2009, Aeterna had only $38.1 million in cash on hand. (Compl't ¶ 150.) Following cost-reduction measures, the company's projected burn rate for 2010 remained between $32-34 million, which threatened Aeterna's viability. (Compl't ¶ 150.) In addition, according to plaintiff, Aeterna issued, at prices inflated by defendants' statements concerning perifosine, more than 52.8 million shares in private placements and public secondary offerings, thereby generating proceeds exceeding $86.5 million. (Compl't ¶ 151.) Plaintiff alleges that Aeterna "sharply increased" compensation for

defendants Engel, Turpin and Blake from 2010 to 2011, and asserts that this is additional evidence of scienter. (Compl't ¶¶ 152-54.)

These allegations do not raise a cogent and compelling inference of scienter. While alleging that the defendants had the expertise and authority to serve on the Coordinating Committee (Compl't ¶ 148), the Complaint does not allege that they actually were members of the committee. Even if it did, such committee membership does not raise an inference of scienter. See, e.g., Plumbers' Union Local No. 12 Pension Fund v. Swiss Reinsurance Co., 753 F. Supp. 2d 166, 185-86 (S.D.N.Y. 2010) (Koeltl, J.) (mere membership in executive risk-monitoring committee is insufficient to support scienter allegations, absent allegations that members knew of red flags that contradicted public statements). Allegations of a defendant's experience and expertise also are insufficient to raise an inference of scienter. See, e.g., Bd. of Trs. of City of Ft. Lauderdale Gen. Emps.' Ret. Sys. v. Mechel OAO, 811 F. Supp. 2d 853, 873 (S.D.N.Y. 2011) (Sullivan, J.) (allegations of "extensive experience" and strong "educational backgrounds" do not support an inference of scienter), aff'd, 475 Fed. Appx. 353 (2d Cir. Apr. 11, 2012).

Plaintiff repeatedly emphasizes that the defendants had access to a free flow of data gained in the perifosine studies, but "broad reference[s] to raw data," which "lack[ ] even an allegation that these data had been collected into reports," is inadequate to allege knowledge that contradicts public statements. Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc., 531 F.3d 190, 196 (2d Cir. 2008). Similarly, there is no factual allegation that the defendants received information that contradicted the seemingly promising results from the Phase 2 testing. The Complaint does not cite to any disputes about the validity of the Phase 2 testing or the existence of internal reports that might have led defendants to challenge the

methods of the perifosine study. See, e.g., Novak, 216 F.3d at 309 ("Where plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information."). The Complaint does not assert that the defendants actually interfered, directly or indirectly, with the actions of the Coordination Committee. There is no factual allegation that defendants guided results, manipulated analysis or exerted improper influence on the Coordinating Committee, and instead merely suggests that they were in a position to do so.

Considering "all the allegations holistically," Tellabs, 551 U.S. at 326, the Complaint fails to raise an inference of scienter based on defendants' expertise, experience and positions within the company.

Plaintiff's scienter allegations also fail to account for the essential role that Keryx played in all aspects of the Phase 2 and Phase 3 trials. As alleged in the Complaint, while Keryx and Aeterna "agreed to be jointly responsible for the pharmaceutical development of perifosine and jointly liable for the costs of development," ultimately, "Keryx was responsible for conducting and testing perifosine in North America . . . ." (Compl't ¶ 32; see also Compl't ¶ 84 (quoting Aeterna press release stating that "[t]he [Phase 3] trial is sponsored and conducted by Keryx Biopharmaceuticals.").) A separate representation cited in the Complaint states that Keryx was conducting the research, with Aeterna given access to the results and underlying data: "Keryx is responsible, in accordance with the terms of our license agreement, for the North American development and registration of perifosine. We have access to all corresponding data at no additional cost." (Compl't ¶ 74.) The class period begins on the date when Keryx –not the defendants – presented the initial, allegedly misleading Phase 2 results to the American Society of Clinical Oncology. (Compl't ¶¶ 54-55.) Several of defendants' allegedly misleading

statements merely repeat Keryx's findings and presentations. (See, e.g., Compl't ¶¶ 60, 64, 107.) Keryx, and not the defendants, "reported *a statistically significant benefit in survival* from updated results of a Phase 2 study of perifosine in the treatment of advanced metastatic colorectal cancer." (Compl't ¶ 87; emphasis in original.) Keryx also conferred with the FDA on the design of the Phase 3 protocol, following Keryx's presentation of the Phase 2 results.[8] (Compl't ¶ 67.) Defendant Engel publicly stated that, pursuant to Keryx's estimate, the Phase 3 trial was expected to complete in 2011. (Compl't ¶ 102.) Plaintiff does not challenge defendant Blake's representation that Aeterna played a "supporting" role in Keryx's work in "setting up and executing their studies."[9] (Compl't ¶ 102.) Accepting the truth of the Complaint's allegations, Keryx was responsible for all major aspects of the design and execution of the perifosine trials, and the Complaint's failure to connect Keryx responsibilities with defendants' alleged manipulations not only weighs against an inference of scienter, but comes close to rendering plaintiff's scienter theories incoherent.

In addition, the Complaint quotes representations that the Phase 3 trial was administered by "an investigational team" of medical researchers who were employed by outside facilities. The Phase 2 trial was "conducted at 11 centers across the United States," and the Phase 3 trial was conducted at 60 sites. (Compl't ¶¶ 69, 118.) As stated in a press release concerning the Phase 3 trial: "Dr. Johanna Bendell, Director of GI Oncology Research for the

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[8] The Complaint quotes defendant Engel stating in a conference call that "Keryx initiated a dialogue with the FDA for the design of a Phase 3 protocol for perifosine for the treatment of metastatic colon cancer, following the positive Phase 2 results reported at ASCO this year." (Compl't ¶ 67.) The Complaint also cites a statement from Aeterna citing the FDA approval of Keryx's application to proceed with the Phase 3 study, and a representation that the Phase 2 results "were reported by Keryx." (Compl't ¶ 74.) Plaintiff does not allege that these statements were untrue.

[9] Specifically, when asked by an analyst to describe Aeterna's role in the Phase 3 study, Blake stated: "I think we have, from our perspective, a very strong and productive relationship with Keryx. It is very harmonious. It is very efficient. They are excellent at setting up and executing their studies. I think we are very good at supporting that, so we're helping them, as Jurgen said, with a lot of the behind the scenes work, a lot of the clinical writing. And we have ourselves had quite an experience with perifosine, so it's a good joint effort between Keryx and us." (Compl't ¶ 102.)

Sarah Cannon Research Institute, Nashville, Tennessee, will lead the Phase 3 investigational team that includes Dr. Cathy Eng, Associate Medical Director for the Colorectal Center at MD Anderson Cancer Center in Houston, Texas." (Compl't ¶ 71.) Frequently, pharmaceutical companies utilize outside facilities to conduct independent studies as to the safety and efficacy of a potential new drug. See generally Suthers v. Amgen, Inc., 372 F. Supp. 2d 416, 418-23 & n.3 (S.D.N.Y. 2005) (discussing role of independent researchers in medical trials). At least as to the Phase 3 trial, the Complaint includes representations that research was overseen by an investigational team of individuals who were affiliated with neither Keryx nor Aeterna, further distancing defendants from the perifosine trial.

As to motive, plaintiff characterizes Aeterna's stock offerings as "desperate measures" to preserve the company when it was "on the brink of insolvency," while also protecting officer bonuses. (Opp. Mem. at 31-33.) However, as noted, "[m]otives that are common to most corporate officers, such as the desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation, do not constitute 'motive' for purposes of this inquiry." ECA, Local 134, 553 F.3d at 198. Indeed, based on defendants' public filings, which are properly considered on a motion to dismiss, the individual defendants increased their holdings in Aeterna shares during the class period. (Kravitz Dec. Exs. M-O.) Chief Judge Preska has described such conduct as "wholly inconsistent with fraudulent intent." In re Bristol-Myers Squibb Sec. Litig., 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004).

In light of the foregoing, the Complaint fails to raise a strong inference of scienter, one that is at least as cogent and compelling as any opposing inference that could be drawn from the facts alleged. Tellabs, 551 U.S. at 324.

III. Plaintiff's Section 20(a) Claim Is Dismissed.

"In order to establish a prima facie case of liability under § 20(a), a plaintiff must show: (1) a primary violation by a controlled person; (2) control of the primary violator by the defendant; and (3) that the controlling person was in some meaningful sense a culpable participant in the primary violation." Boguslavsky v. Kaplan, 159 F.3d 715, 720 (2d Cir. 1998) (quotation marks omitted).

Because the Complaint fails to plead a primary violation, the Section 20(a) claim is dismissed.

PLAINTIFF'S MOTION TO STRIKE IS DENIED.

Plaintiff moves to strike certain exhibits attached to the affidavit of Robert N. Kravitz, asserting that they are not incorporated by reference or integral to the Complaint, and that they are not matters of public record properly subject to judicial notice. Plaintiff asserts that these "extraneous documents" are inadmissible hearsay that should not be considered on a motion to dismiss. Specifically, plaintiff argues that Exhibits A-B, D, G and I-O should be excluded. (Docket # 26, 27.) Defendants have submitted arguments in opposition, and plaintiff filed no reply.

The exhibits challenged by the plaintiff include guidance and pronouncements from government agencies, and filings made to government agencies, the authenticity of which is not in dispute. See Kravitz Aff't Exs. A (FDA Guidance to Industry, May 2007), B (printouts from National Institutes of Health website, ClinicalTrials.gov), G (FDA Guidance for Industry, May 2002), I (Scientific Advice and Protocol Assistance issued by the European Medicines Agency), J (printout from FDA website explaining drug-review process), K (FDA Guidance for Industry, January 2006), L (printout from National Institutes of Health website,

ClinicalTrials.gov), M-O (record of stock transactions filed with Canada's System for Electronic Disclosure by Insiders). Exhibit D, an article published in the Journal of Clinical Oncology that describes the results of the Phase 2 trial, is the only challenged exhibit that is neither a regulatory filing nor an agency pronouncement. (Kravitz Aff't Ex. D.)

As an initial matter, the Court has relied on only a handful of these exhibits. Specifically, it has relied on the history of amendments to changes in the study's protocol, in versions that both were submitted by defendants (Exs. B & L) and available online through the National Institutes of Health at ClinicalTrials.gov. The Court also has relied on individual defendants' filings with the Canadian Securities Administrators, a Canadian agency similar to the SEC. (Exs. M-O.) Separately, the Court relied on FDA guidance as to the agency's definition of a double-blind study, which was not submitted by the defendants, but is available through the agency website. These documents were integral to the Complaint's allegations, and are published by government sources from which the Court may appropriately take judicial notice.

Defendants appropriately submitted the FDA's "Guidance to Industry" circulars, and the Court has relied on such a circular in reviewing the plaintiff's allegations. As discussed, plaintiff alleges that the defendants misleadingly described the Phase 2 trial as double blind. But the Complaint proposes no definition of what constitutes a double-blind trial. Without such a definition, there is no basis to meaningfully review the basis of plaintiff's claims. They would be either unintelligible, or based on plaintiff's undefined, ipse dixit understanding of double-blind methodology. Indeed, in his opposition memo, the plaintiff himself relies on the FDA's same definition of a double-blind study, (Opp. Mem. at 15) and separately relied on other FDA industry guidance in the Complaint. (Compl't ¶ 42.) Contrary to the rationale articulated in

plaintiff's motion to strike, the Court has not relied on the FDA statements to draw factual inferences as to the FDA's views of the Phase 2 trial. (Strike Mem. at 8.) Moreover, it is appropriate for a court to take judicial notice of the FDA's published guidance to industry. See, e.g., Gale v. Smith & Nephew, Inc., __ F. Supp. 2d __, 2013 WL 563403, at *1 n.2, *5 n.6 (S.D.N.Y. Feb. 13, 2013) (Bricetti, J.) (taking judicial notice of FDA's published statements); Peviani v Hostess Brands, Inc., 750 F. Supp. 2d 1111, 1116 (C.D. Cal. 2011) (taking judicial notice of non-binding FDA guidance on nutritional labeling).

Similarly, it is appropriate to review the versions of the studies' designs as published and available online through the National Institutes for Health at ClinicalTrials.gov. (Exs. B & L.) As discussed Complaint asserts that the defendants misstated and omitted material aspects of the Phase 2 and Phase 3 trials, including their endpoints and the numerous research arms of the first stage to Phase 2 trial. Review and consideration of the trials' published amendments are necessary to identify defendants' alleged misstatements and omissions, or lack thereof. Plaintiff's motion to strike goes solely toward what he considers the proper interpretation of these designs, before proceeding to argue that the published designs actually strengthen his fraud theory. (Strike Mem. at 5-6.) The Court has not considered these amendments for the truth contained therein, but to compare the trials' publicly disclosed descriptions with the alleged misstatements and omissions asserted by plaintiff. This information is both integral to the Complaint's allegations and properly subject to judicial notice. See, e.g., Kavowras v. N.Y. Times Co., 328 F.3d 50, 57 (2d Cir. 2003) (judicial notice may be taken of public filings made to the NLRB); Kramer v. Time Warner Inc., 937 F.2d 767, 774 (2d Cir. 1991) (judicial notice may be taken of public filings to the SEC).

Lastly, plaintiff argues that the Court should not consider the individual defendants' filings with Canadian authorities as to their acquisition of Aeterna shares during the class period. (Exs. M-O.) As stated in his memorandum, "For all intents and purposes, disclosures under SEDI in Canada is [sic] the functional equivalent of disclosure under SEC Form 4 in the United States." (Id. at 8 n.15.) But courts in this District routinely take judicial notice of Form 4 filings at the motion to dismiss stage, and consider them for the truth of their contents. See, e.g., In re Bear Stearns Companies, Inc. Sec., Derivative & ERISA Litig., 763 F. Supp. 2d 423, 583-84 (S.D.N.Y. 2011) (Sweet, J.) (collecting cases); see also Kramer, 937 F.2d at 774 (courts may properly take judicial notice of SEC filings).

Because the remaining exhibits that plaintiff challenges played no role in the Court's review of defendants' motion, I need not address his arguments directed to those exhibits. The motion to strike is otherwise denied.

ENTRY OF FINAL JUDGMENT IS APPROPRIATE.

The motion to dismiss is directed to the third complaint that has been filed in this action, each of which proposed different theories of defendants' liability. The initial complaint was directed solely to the Phase 3 trial, and alleged that defendants knew or should have known that the Phase 3 trial would conclude later than the fourth quarter of 2011. (Docket # 1.) The Amended Securities Class Action Complaint (Docket # 15) alleged that defendants misrepresented the Phase 2 trial results as positive and statistically significant, raising many of the same contentions that were later incorporated into the Second Amended Securities Class Action Complaint. (See, e.g., Docket # 15 ¶¶ 45-51.) Plaintiff also alleged that defendants omitted material information by not identifying a specific chemotherapy agent as a potential competitor to perifosine, misleadingly described perifosine as "novel," misled investors about

the availability of generic capecitabine and misled investors about the timing of the Phase 3 trial results. (See, e.g., Id. ¶¶ 116-17, 122-23, 134-35, 138-39, 141-42, 161.)

The parties attended an initial pretrial conference on December 7, 2012. (See Minute Entry.) In an Order issued that same day, the Court noted that plaintiff had availed itself of the opportunity to review defendants' pre-motion letter dated December 5, 2012. (Docket # 17.) The Order set a schedule for the present motion, and stated: "Plaintiff has been offered a final opportunity to amend and may elect to do so." (Docket # 17.) Plaintiff filed the Second Amended Class Action Securities Complaint on December 21, 2012. (Docket # 18.) Plaintiff's memorandum of law in opposition to this motion makes no mention of seeking leave to amend.

Plaintiff has already had two opportunities "to plead fraud with greater specificity." Luce v. Edelstein, 802 F.2d 49, 56 (2d Cir.1986). In this instance, the plaintiff also filed the Second Amended Securities Class Action Complaint after reviewing the bases for defendants' proposed motion, but failed to satisfy the pleading requirements of Rule 9(b) and the PSLRA. Entry of judgment is appropriate in this case.

CONCLUSION

Defendants' motion to dismiss is GRANTED. (Docket # 22.) Plaintiff's motion to strike is DENIED. (Docket # 26.)

The Clerk is directed to terminate the motions and to enter judgment for the defendants.

SO ORDERED.

P. Kevin Castel
United States District Judge

Dated: New York, New York
May 29, 2013